4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2021-F-0564]

Biomin Holding GmbH; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Biomin Holding GmbH, proposing that the food additive regulations be amended to provide for the safe use of fumonisin esterase to degrade fumonisins in poultry feed. **DATES:** The food additive petition was filed on May 20, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Wasima Wahid, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-221), Rockville, MD 20855, 240-402-5857, Wasima.Wahid@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 2314), submitted by Biomin Holdings GmbH, Biomin Research Center, Technopark 1, 3430 Tulin, Austria. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of fumonisin esterase to degrade fumonisins in poultry feed.

The petitioner has claimed that this action is categorically excluded under 21 CFR

25.32(r) because it is of a type that does not individually or cumulatively have a significant effect

on the human environment. In addition, the petitioner has stated that, to their knowledge, no

extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an

environmental assessment nor an environmental impact statement is required. If FDA

determines a categorical exclusion does not apply, we will request an environmental assessment

and make it available for public inspection.

Dated: June 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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